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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/800,070	03/06/2001	Yves Delmotte	WM-252.00	4142

7590 07/14/2004

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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 07/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/800,070	DELMOTTE, YVES	
	Examiner	Art Unit	
	Isis Ghali	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 April 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *37-64,66-77 and 79-92* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *37-64,66-77 and 79-92* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *04/14/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The receipt is acknowledged of applicant's amendment, both filed 04/22/2004.

Claims 65 and 78 have been canceled, and claims 85-92 have been added.

Claims 37-64, 66-77, 79-92 are pending in the prosecution.

The following action is necessitated by applicant's amendment:

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 37-64, 66-77, 79-81, drawn to elongated structure and method of its production, classified in class 424, subclass 443.

   II. Claims 82-92, drawn to process for manufacturing fibrin material, classified in class 424, subclass 449.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of

operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions has different effects as they produce two different materials. The invention of group I is directed to an elongated structure and the method of its production, while the process of invention II is not necessary result in elongated structure, but results in gel material.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 37-64, 66-77, 79-81 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application

was filed, had possession of the claimed invention. The amendment of the claims to recite "solely mammalian derived" has introduced new matter. Recourse to the specification revealed no disclosure of the fibrin material as solely mammalian derived. Furthermore, the new method claimed in claims 57-64, 66-77, 79-81 introduced new matter by reciting steps not disclosed in the original specification. These steps are applying positive, pressure, freeze-drying and removing free water.

Claim Rejections - 35 USC § 102

3. Claims 37-39, 44-46, 48-50, 56-58, 62-64, 66-69, 70-77, 79-84 rejected under 35 U.S.C. 102(b) as being anticipated by Dinh, US 5,510,077 ('077).

US '077 disclosed porous antithrombic fibrin stent that is longitudinally stretched reads on claims 37-39 (abstract, col.3, lines 6-9; col.8, lines 21-23). The fibrin is in the form of fibril and forms tube having internal diameter of 2.7 to 3.4 mm, reads on claim 44, 48-50, 78, and 79 (col.3, line 1, col.10, lines 47-49). The fibrin is cross-linked, claim 56 (col.3, lines 5-63). The reference disclosed a method of making the stent comprising generating the fibrin gel from fibrinogen by the action of thrombin, and longitudinally stretching the stent, reads on claims 57, 58, and 69 (col.3, lines 55-65; col.4, lines 1-7; col.8, lines 20-23, 33-54; col.9, lines 65-67; col.10, lines 1-2). The process of making above included the step of drying and dehydration, claims 62 and 68 (col.10, line 59). The composition is molded into a stent and stretched mechanically using pressure or balloon, that stretch the tube in two directions, and the composition is lyophilized, claims 63-67, 77, 80 and 81, 84 (col.10, lines 12-65). The concentration of fibrinogen in the

composition is 26 mg/ml and thrombin is present in an amount of 1-120 IU/ml, claims 70-74 (col.5, lines 3-6; col.10, lines 1-3). The composition comprising calcium and drugs, such anticoagulant or anti-inflammatory, etc., claim 75 and 76 (col.4, lines 7-10, 29; col.5, lines 11-16; col.6, lines 3-15). The composition comprises water that is removed from the composition, claim 68, 82-83 (col.4, lines 40-55). The reference disclosure reads on the self-supported fibrin material because composition having the same ingredients will inherently have the same functional properties.

Claim Rejections - 35 USC § 103

4. Claims 37-64, 66-77, 79-92 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '077.

The reference teaches the porous fibrin stent made of fibrinogen by the process of the instant claims.

The reference does not teach the different densities and the degree of the difference between the densities, claims 40-43. However, the claimed densities are not considered critical, absent evidence to the contrary. One having ordinary skill in the art would have achieved the claimed densities based on the motivation of providing different thickness, different degree of mechanical properties and biostability of the device.

The reference dos not teach diameter of the 100-2500 micrometer, claims 47, 51, or the wall thickness of claims 52 and 53. However, the claimed diameter of 2500 is not considered patentable over the prior are diameter of 2.7 (2700 micrometer), absent

evidence to the contrary. It is obvious to one having ordinary skill in the art to select the thickness of the tube, as well as the diameter, based upon the blood vessel where the stent would be inserted and the strength of the blood flow in this vessel.

The reference does not teach the amount of fibrin, claim 55. However, the amount of fibrin does not impart patentability to the claims, absent evidence to the contrary. It is expected to have the same amount of fibrin in the composition of the prior art that has the same amounts of the starting material and the converting material as in the instant claims.

The reference does not teach the degree of stretching of the length, claim 59-61. The degree of stretching does not impart patentability to the claims, absent evidence to the contrary. However, the reference disclosed that fibrin is fragile and the expansion should be controlled to obtain the stent with proper dimensions for expansion in vivo without tearing.

Thus, it would have been obvious to one having ordinary skill in the art a the time of the invention to deliver a fibrin material that is stretched longitudinally as disclosed by the reference, and adjust the densities, diameters and the thickness of the wall, and the degree of stretching of the material according to particular site of application, motivated by the teaching of the reference that fibrin is fragile and the expansion should be controlled to obtain the a material with proper dimensions for expansion in vivo without tearing, with reasonable expectation of having an elongated fibrin structure that is useful for vascular and wound treatment.

Response to Arguments

5. Applicant's arguments filed 6/30/2003 have been fully considered but they are not persuasive.

Applicant traverses the rejection of claims 37-39, 44-46, 48-50, 56-58, 62-69, and 70-84 as being anticipated under 35 U.S.C. 102(b) by US '077; and the rejection of claims 37-84 as being obvious under 35 U.S.C. 103(a) in view of US '077 by arguing that US '077 fails to teach or suggest an elongated structure composed of a solely mammalian derived fibrin material Longitudinally stretched as recited in claims 37 and 57, for example. Rather, the reference discloses a method for making a fibrin stent by radially compression a fibrin material against a mold surface. The skilled artisan will recognize that the compression method yields a thin, compacted fibrin structure that is too fragile to be stretched. Moreover, the synthetic stent composed of a polyurethane/fibrin blend and not solely mammalian-derived fibrin material recited in the present claims.

In response to the above argument, the examiner position is that the reference disclosed a fibrin stent having the same composition and produced by the same process as claimed by the applicant. The specification does not provide any support or disclosure of the fibrin is solely mammalian derived. The stent is an elongated structure. The reference disclosed the stretching by compression and molding of the fibrin material, as claimed by applicant, absent support to positive pressure from the specification. Note that a comprising-type language does not exclude other elements or

materials, and permits the presence of the polyurethane, absence of support from the specification. *Cues Inc. vs. Polymer Industries*, USPQ 2d 1847 (DC ND GA 1988).

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isis Ghali
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Art Unit 1615

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